MAR 3 0 2000

K000018

VII. 510(k) SUMMARY

A. Manufacturer Information:

Submitter's Name:	Nobel Biocare USA, Inc. 22825 Eastpark Drive Yorba Linda, CA 92887 USA
Contact's Name:	Kathleen Dragovich Regulatory Affairs Specialist 714-282-4800, extension 7832
Manufacturer's Address:	Nobel Biocare AB Dimbovagen 2 Karlskoga S-691-51 SWEDEN
Mfg's Registration No.	9611993

B. Device Name:

Common Name:	Dental Implant
Trade Name:	Brånemark Novum

C. Classification:

Classification Name:	Endosseous Dental Implant
Classification Number:	DZE
Classification Citation:	21 CFR 872.3640

C. Device Description:

These devices make up a system for the treatment of totally edentulous mandibles. The mandible system is used, between the foramina, on totally edentulous mandibles, with a minimum height of 13mm and a minimum width of 6mm. By the aid of different guides and templates, three fixtures are placed in an exact and predetermined position, corresponding to the pre-designed prosthetic bars that are used. The system also allows for the prosthetic reconstruction to be completed and connected to the implants at the same day as they are installed. The fabrication of the supra structure will be performed without any impressions taken.

D. Intended Use:

Totally edentulous mandibles with a minimum height of 13mm and a minimum width of 6mm. Patient must be subject to dental treatment with endosseous implants.

E. Rationale for Substantial Equivalance

A. Intended Uses: Comparison of Predicate Products and Submitted Product.

The Brånemark Novum, the Steri-Oss Smooth Staple Implant, and the ITI One Part Implants are all intended for use in edentulous mandibles in conjunction with bar-borne superstructures. All are indicated for immediate load.

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 0 2000

Ms. Kathleen Dragovich
Regulatory Affairs Specialist
Nobel Biocare USA, Inc.
22895 Eastpark Drive
Yorba Linda, California 92887

Re: K000018
Trade Name: Brånemark Novum
Regulatory Class: III
Product Code: DZE
Dated: December 30, 1999
Received: January 4, 2000

Dear Ms. Dragovich:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your

premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4690. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

X. INDICATIONS FOR USE

510(k) Number (if known): K K000018

Device Name: Brånemark Novum

Indications For Use:

Totally edentulous mandibles with a minimum height of 13mm and a minimum width of 6mm. Patient must be subject to dental treatment with endosseous implants. For use in a single stage procedure where the implants are immediately loaded.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____

(Per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000018